# **Rizatriptan Formulation**



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#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Rizatriptan Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.

Address : Avenida 16 de Septiembre No. 301

Xaltocan - Xochimilco Mexico 16090

Telephone : 52 55 57284444 Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure (Oral)

Category 1 (Cardio-vascular system)

**GHS label elements** 

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.

H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

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P501 Dispose of contents/ container to an approved waste dis-

posal plant.

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 50 -< 70
Starch	9005-25-8	>= 10 -< 20
Rizatriptan	145202-66-0	>= 5 -< 10

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water. Suspected of damaging the unborn child.

Most important symptoms

and effects, both acute and

Protection of first-aiders

delayed

Causes damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

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> Dry chemical None known.

Unsuitable extinguishing

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions** Avoid release to the environment.

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling

Do not breathe dust.

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Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Rizatriptan	145202-66-0	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

**Engineering measures** : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds

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are required to control at source and to prevent migration of

the compound to uncontrolled areas (e.g., open-face

containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : pink

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower

flammability limit

No data available

No data available Vapor pressure

Relative vapor density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle size No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

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**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

**Components:** 

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Rizatriptan:

Acute oral toxicity : LD50 (Rat): 2,227 mg/kg

LD50 (Mouse): 700 - 1,631 mg/kg

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Rizatriptan:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Starch:

Species : Rabbit

Result : No eye irritation

Rizatriptan:

Species : Bovine cornea

Remarks : Moderate eye irritation

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#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Rizatriptan:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitization.

Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Rizatriptan:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Alkaline elution assay

Result: negative

Test Type: In vitro mammalian cell gene mutation test



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Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

#### Rizatriptan:

Species : Mouse Application Route : Oral

Exposure time : 100 weeks

NOAEL : 125 mg/kg body weight

Result : negative

Species : Rat
Application Route : Oral
Exposure time : 106 weeks

NOAEL : 106 mg/kg body weight

Result : negative

#### Reproductive toxicity

Suspected of damaging the unborn child.

# Components:

#### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Rizatriptan:

Effects on fertility : Test Type: Fertility/early embryonic development

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Species: Rat, female Application Route: Oral

Fertility: LOAEL: 100 mg/kg body weight

Symptoms: altered estrus cycles

Result: No effects on fertility and early embryonic

development were detected.

Test Type: Fertility/early embryonic development

Species: Rat, male Application Route: Oral

Fertility: NOAEL: 250 mg/kg body weight

Result: No effects on fertility and early embryonic

development were detected.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: No teratogenic effects., Embryo-fetal toxicity.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: No teratogenic effects., Embryo-fetal toxicity.

Remarks: The effects were seen only at maternally toxic dos-

es.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### **STOT-single exposure**

Not classified based on available information.

#### **Components:**

#### Rizatriptan:

Assessment : May cause drowsiness or dizziness.

# STOT-repeated exposure

Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

#### **Components:**

#### Rizatriptan:

Target Organs : Cardio-vascular system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

# Public

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#### Repeated dose toxicity

#### **Components:**

Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Rizatriptan:

Species : Rat
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species : Dog

LOAEL : 0.05 mg/kg
Application Route : Intravenous
Exposure time : 2 Weeks

Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species : Dog LOAEL : 0.2 mg/kg Application Route : Oral Exposure time : 1 y

Symptoms : Dilatation of the pupil

### **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

#### **Components:**

Rizatriptan:

Ingestion : Target Organs: Cardio-vascular system

Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness,

**Drowsiness** 

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#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Rizatriptan:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 48

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.6 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 110 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.



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Rizatriptan:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 50 % Exposure time: 13 d

Method: OECD Test Guideline 314

**Bioaccumulative potential** 

**Components:** 

Rizatriptan:

Partition coefficient: n-

octanol/water

log Pow: -0.649

Mobility in soil

**Components:** 

Rizatriptan:

Distribution among environ-

mental compartments

log Koc: 3.83

Method: OECD Test Guideline 106

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Dispose of in accordance with local regulations. Waste from residues

Contaminated packaging Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

International Regulations

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

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#### **SECTION 15. REGULATORY INFORMATION**

# Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

Not applicable

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

AIIC - Australian Inventory of Industrial Chemicals: ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tempera-

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ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8